Department of Labor and Industries
Office of the Medical Director
Health Technology Assessment
Meniscal Allograft

I. Background

Meniscal allograft transplantation is a surgical treatment that involves grafting a donor meniscus into the knee of a patient. Patients who have undergone previous meniscectomy may benefit from the procedure because the replacement meniscus may reestablish load bearing, shock absorption, and joint stability. Reducing stress on the tibial plateau may also help to prevent osteoarthrosis development. (Menetrey 1999) (Messner 1999b)

Surgeons may choose grafts according to harvest and preservation methods. The meniscus from a non-genetically related donor can be harvested through either aseptic or clean techniques. Aseptic harvesting involves maintaining the sterility of the graft during harvest and processing. Because clean harvesting does not require sterile processing, chemical agents or gamma irradiation is used for secondary tissue sterilization.

Allograft preservation occurs through:
1. cooling and fresh transplantation within 24 hours.
2. fresh-freezing.
3. cryopreserving the tissue through controlled-rate freezing with extraction of cellular water.
4. freeze-drying (lyophilizing) with or without cryopreservation.

Fresh tissue may allow fibrochondrocytes to preserve the extracellular matrix whereas frozen tissue is acellular. In addition, cryopreservation may damage the cartilage matrix during freezing and lyophilized allografts tend to shrink. However, disease transmission remains a significant consideration, especially for fresh-frozen grafts. (Messner 1999a) (Shelton 1998a)

The effect of cell repopulation on transplants remains uncertain. Viable donor cells might benefit the mechanical properties of allograft as repopulation may render the transplanted meniscus more susceptible to injury. However, the allograft may act as a scaffold for host cells allowing for increased healing. (Debeer 2000) (Johnson 1999) Bylski-Austrow observed that meniscal allografts showing the greatest degree of cell repopulation least effectively distributed load. In contrast, the grafts distributing contact stresses well had not experienced cell repopulation and had not healed. Although the grafts had remained structurally intact, non-vital grafts tend to deteriorate. (Messner 1999b)

II. Patient Selection

Published literature indicates that patients who may benefit from meniscal allograft transplantation have the following characteristics:
1. Are too young or active for arthroplasty. Ideal patient age generally ranges from 20 to 40 years.
2. Experience knee pain unresponsive to conservative treatment.
3. Have undergone meniscectomy. Operative reports, magnetic resonance imaging, or diagnostic arthroscopy establishes the absence of the meniscus.
4. Have sufficient articular cartilage in the affected compartment. The quality and quantity ensures that an irregular surface will not damage the new meniscus. The joint should not have degenerated to Outerbridge Grade III or IV as determined by posterolateral radiographs.
5. Have ligamentous stability and normal alignment. Standing, full-length radiographs indicate varus or valgus deformity. (Johnson 1999) (Shelton 1994) (Shelton 1998b) (Veltri 1994) (Verdonk 1999a)

III. Tissue Regulation

The Food and Drug Administration (FDA) does not monitor surgical procedures like meniscal allograft transplantation. However, in December 1993, the FDA began regulating criteria for tissue donor selection and conducting site visits of tissue banks.

An example of the FDA's regulatory authority in the area of tissue banks occurred in 2002. The FDA ordered CryoLife, a human tissue-processing firm, to recall human allograft tissue processed since October 3, 2001. The FDA issued the order after discovering regulatory violations related to tissue processing and finding that CryoLife had not implemented adequate corrective actions. The FDA determined that CryoLife could not ensure the absence of fungal and bacterial contaminants in its tissues. (CDER 2002)

The American Association of Tissue Banks (AATB) initiated a program of Inspection and Accreditation of tissue banks in 1986. Based upon association standards and procedures, tissue banks receive accreditation for their operations including tissue retrieval, processing, storage, and distribution. The association inspects tissue banks for compliance in record keeping, quality control, quality assurance, donor and tissue suitability determination, and safety. Finally, the cadaveric donor must pass a history questionnaire completed by the next of kin, a physical exam, and lab tests. (Shelton 1998a) At present, AATB has accredited 72 tissue banks in the United States. (AATB undated)

IV. Evidence

A. Peer-reviewed journals have published one study of meniscal allografts that includes comparison groups. Wirth's prospective study examines the results of medial meniscal transplantation combined with anterior cruciate ligament (ACL) reconstruction at 3 and 14-year follow-up.[1] (Wirth 2002) The study also included 2 comparison groups chosen randomly by computer.

Study Population: Researchers examined 23 patients (average age 29.6 years) with a history of medial meniscectomy and anterior knee instability. Complete medial meniscectomy had occurred in 18 subjects. Researchers used lyophilized allografts in 17 cases and deep frozen allografts in 6 cases.

Comparison Groups: All comparisons underwent ACL reconstruction. The first group consisted of 11 subjects who had previously undergone meniscectomy. The second group consisted of 10 patients with intact menisci.

Results: Lysholm scores for the study population increased from 59 at baseline to 84 at 3 years. At 14 years, subjects had an average score of 75. The meniscectomy comparison group had higher Lysholm scores than the lyophilized transplant subjects. However, the researchers indicate that transplant subjects' cartilage initially showed more severe deterioration.

Preoperatively, 14 patients had Fairbanks Grade I or II degenerative changes. At 14-year follow-up, 6 patients had Grade II changes and 5 had Grade III changes. The patients with arthrotic changes had all received lyophilized menisci.

Researchers conducted second-look arthroscopies in 19 patients an average of 3.8 years after transplantation. Thirteen out of 14 lyophilized allografts decreased in size by at least one-third due to degenerative changes. Two out of 5 frozen allograft subjects had transplants that reduced in size by one-third.

At 14 years, researchers performed additional MRI in 9 subjects (3 deep-frozen and 6 lyophilized). Subjects with deep-frozen menisci did not show further shrinkage when compared to 3-year follow-up. Of the lyophilized menisci recipients, 2 experienced shrinkage and 5 had Grade III-IV chondromalacia.

Conclusion: Patients experienced a slight deterioration over the years. Deep-frozen grafts were consistently superior to lyophilized grafts.

[1] Study populations overlap between the 2002 Wirth and 1989 Milachowski studies. Milachowski conducted 22 menisci transplants in patients with Grade II or III instability. (Milachowski 1989) Follow-up time averaged 13 months. The 22 patients received either frozen (6) or lyophilized (16) allografts. Researchers examined 20 subjects using clinical criteria. After an average of 13 months, 18 out of 20 subjects had satisfactory clinical outcomes. After an average of 8 months, 14 subjects agreed to second-look arthroscopy. Although arthroscopy revealed that both lyophilized and deep frozen menisci decreased in size, frozen menisci showed better results. Three treatment failures occurred.

B. Published case series studies had small sample sizes and no control or comparison groups. Follow-up time ranged from 8 months to 64 months. Because subjects often underwent concomitant procedures, evaluating the effect of allograft transplantation alone is difficult.

1. Van Arkel describes a prospective survival analysis of 63 consecutive meniscal allografts.[2] (van Arkel 2002) Clinical criteria for failure included persistent pain or mechanical damage. Follow-up after transplantation averaged 60 months (range 4 to 126 months).

   Study Population: Patients presented with disabling compartmental osteoarthritis and had previously undergone total meniscectomy. A mean of 16 years passed between meniscectomy and transplantation. Researchers implanted 63 meniscal allografts (34 lateral, 17 medial, 6 lateral and medial in the same knee) into 57 patients whose mean age was 39 years.

   Results: The number of subjects with unstable joints decreased significantly from 21 to 11 after transplantation. A significantly negative correlation existed between rupture of the ACL and successful meniscal transplant. A significant difference in clinical results occurred between lateral and medial meniscal transplants.

   Thirteen subjects failed treatment (5 lateral, 7 medial, and 1 medial and lateral). Persistent pain defined failure in 8 patients, and the allograft failed in 5 patients. Cumulative survival rate of the lateral, medial, and combined allografts was 76%, 50%, and 67%, respectively. The mean survival time for lateral, medial, and combined allografts was 111, 69, and 89 months, respectively. When graft survival acted as the endpoint, the cumulative success rate was 88% for the lateral and 63% for the medial allografts.

   Conclusion: The study shows that lateral allografts lasted longer and had fewer failures than medial allografts.

[2] Study populations in van Arkel's 1995 and 2002 studies overlap. In 1995, van Arkel evaluated 23 subjects (average age 41 years) who received cryopreserved meniscal transplants. (van Arkel 1995) Fourteen subjects received lateral menisci, 7 received medial menisci, and 2 received both. An average of 16 years elapsed between meniscectomy and transplant. At average 36-month follow-up, 20 subjects scored Fair and Good while 3 scored Poor on the Lysholm scale. Average Lysholm scores increased from 26 to 75, and Tegner scores increased from 2 to 3. Of the 12 patients who agreed to second-look arthroscopies, 7 subjects healed to the knee capsule. The researchers conclude that the allograft attaches to the knee capsule and undergoes revascularization. De Boer describes the three treatment failures in a 1994 publication.

2. Verdonk examined Hospital for Special Surgery (HSS) scores after an average follow-up of 5 years 4 months.[3] (Verdonk 2002)

   Study Population: Within a 12-year period, 98 patients underwent meniscal allografts. Of the 98 subjects, researchers included 78 patients in a 10-year follow-up. After excluding 9 patients due to total arthroplasty for progressive osteoarthritis (5) and losses to follow-up (4), 69 subjects remained.

   Results: Of the 69 subjects, 62% resumed their original work. 87% of patients said they would undergo transplantation again if necessary. The 69 subjects had an average preoperative HSS score of 113. At follow-up, 79% scored more than 175 points and 21% scored from 100 to 175. Preoperative and postoperative pain scores improved significantly. Researchers did not detect differences in HSS scores or pain relief between medial and lateral transplants.

3. Rath prospectively evaluated subjects 2 to 8 years after transplantation. (Rath 2001)

   Study Population: Researchers transplanted 27 cryopreserved meniscal allografts into 23 patients who had meniscectomies an average of 7.7 years earlier. Five patients were lost due to attrition leaving 22 transplants (15 medial and 7 lateral) at follow-up.

   Results: After an average of 54 months, subjects experienced decreases in pain and limited improvement in function. Eleven radiographs showed that compartment space decreased from 5.2 mm before transplant to 4.5 mm at follow-up.

   After 31 months, 8 allograft menisci (36%) tore resulting in 6 partial and 2 total meniscectomies. Histological exams of the torn and failed allografts suggested that fewer cells repopulate allografts than in normal menisci. In addition, the cells demonstrated decreased biologic activity, such as decreased growth factor production.

   Conclusion: Allograft menisci successfully alleviate compartmental pain caused by meniscectomy. However, fewer cells repopulate the graft. The cells also demonstrate reduced function, which may contribute to the high frequency of retears noted in the study.

[3] Patient populations in Verdonk's 1997 study overlap with the 2002 study. In 1997, Verdonk published data on 40 transplants after a mean follow-up of 3 years. (Verdonk 1997) The study included 36 patients who underwent transplant of the medial (23) or lateral meniscus (17). Researchers performed transplantation alone (24), transplantation and valgus osteotomy (10), transplantation and ACL repair (1), and transplantation and varus osteotomy (1). Researchers repeated arthroscopy in 12 patients up to 12 years later. All showed viable meniscal tissue. Subjects showed significant improvement in pain and stability, but no change in range of motion, flexion, or extension. Hospital for Special Surgery scores decreased slowly over time. At year 1, 72% of subjects scored over 175. After 4 years, 67% scored higher than 175, 22% scored between 100 and 175, and 11% scored below 100. Three patients eventually received total knee arthroplasty.

4. Stollsteimer reported on 22 patients who underwent transplantation with nonirradiated, cryopreserved allografts. After an average of 40 months (range 13 to 69 months), researchers prospectively examined Tegner and Lysholm scores, International Knee Documentation Committee ratings, and Outerbridge ratings. (Stollsteimer 2000)

   Study Population: From October 1991 to December 1995, 23 knees that had previously undergone total meniscectomy underwent transplantation (12 lateral and 11 medial). The 22 patients had an average age of 31 years and presented with persistent pain. An average of 45.3 months had elapsed from meniscectomy to transplant (range 3 to 180 months).

   Results: Patients graded their pain as none, mild, moderate, or severe. Researchers found that 5 patients improved 2 grades, 13 subjects improved 1 grade, and 1 subject increased by 1 grade. Patients experienced an average .882 mm (range 0-3 mm) loss of joint space. Four subjects lost 1 mm, and 6 subjects lost 2 mm or more.

   Tegner scores increased insignificantly from 3.4 before transplant to 4.0 after transplant. Lysholm scores increased significantly from 47.2 (range 11-77) to 75.6 (range 43-95). International Knee scores increased for patients who weighed less than 225 pounds and who had Outerbridge ratings below grade II. Researchers also detected an inverse relationship between Outerbridge ratings and improvement in Tegner or Lysholm scores.

   Twelve randomly selected patients underwent MRI to compare the size of the transplant to the intact meniscus in the opposite knee. After an average of 24.4 months, allografts averaged 62% of the normal menisci (range 31% to 100%).

   Some patients developed complications, including 1 graft removal due to pyogenic infection, 1 hemarthrosis, 2 cases of synovitis requiring synovectomy, and 1 loosened bone plug. Furthermore, 5 partial meniscectomies and 1 medial repair occurred in 5 patients at average 14.3 months post-implant.

   Conclusion: Although patients continued to have pain relief following their transplantation, the researchers expressed concern over meniscus shrinkage. They also state that whether the allograft protects the knee from progressive degenerative arthritis remains to be determined.

5. Shelton examined the Lysholm and Tegner scores for 17 patients after an average of 40 months (range 13 to 64 months).[4] (Shelton 1998b)

   Results: The subjects showed improvements in Lysholm and Tegner scores, and 15 subjects indicated excellent subjective pain relief. The 9 subjects who underwent MRI studies showed no peripheral extrusions of the allograft meniscus. However, the transplant had only 71% of the volume of the normal meniscus in the opposite knee.

   Conclusion: Replacing a meniscus with an allograft may restore normal load distribution, lubrication, and stability in the knee. Concerns about graft shrinkage, central hypocellularity, and long-term functional survival remain.

6. Between 1988 and 1994, 80 knees received fresh meniscal allografts. (Cameron 1997) Cameron conducted a retrospective review of the 67 meniscal allograft transplants available for follow-up. Follow-up time averaged 31 months, and researchers assessed outcomes using modified Lysholm and Tegner scales.

   Subjects: The 63 patients had an average age of 41 years and had undergone meniscectomy 16.7 years earlier. The subjects were too young or active for complete arthroplasty and presented with:
   - disabling knee pain refractory to conservative treatment
   - unicompartmental crepitus
   - pain on valgus-varus stress
   - unicompartmental osteoarthritis (Outerbridge Grade II-IV)

   Researcher grouped patients into 6 procedural categories:
   a) isolated meniscal allograft (21)
   b) allograft combined with ACL reconstruction (5)
   c) medial meniscal allograft with valgus high tibial osteotomy (18)
   d) lateral meniscal allograft with varus high tibial osteotomy (10)
   e) lateral meniscal allograft with varus femoral osteotomy (6)
   f) medial meniscal allograft combined with valgus high tibial osteotomy and ACL reconstruction (7).

[4] The study populations in Shelton's 1994 study overlap with the 1998 study. In 1994, Shelton reported on 14 menisci (9 lateral and 5 medial) arthroscopically implanted during a 22-month period. (Shelton 1994) The patients did not experience intraoperative complications. All 14 menisci demonstrated evidence of healing of the periphery and of the bone plugs.

Results:

Number of Good to Excellent Results According to Procedure,
Mean Follow-up of 31 months

Procedure	Number of Knees	Number of Knees with Good to Excellent Results (%)
all procedures	67	58 (86.6%)
allograft only	21	19 (90.5%)
allograft and ACL reconstruction	5	4 (80.0%)
allograft and osteotomy	34	29 (85.3%)
allograft, osteotomy, and ACL	7	6 (85.7%)

Before surgery, 36 patients required analgesics and 39 required anti-inflammatories. After transplantation, the number requiring medication decreased to 12 and 14, respectively. Second-look arthroscopy of the first 10 implanted menisci showed complete peripheral healing without evidence of shrinkage.

Of the 20 knees with more than 3 years follow-up, 17 (85%) received Good to Excellent ratings. On a 100-point scale, overall scores increased from 37 preoperatively to 80 points postoperatively. On the 10-point activity scale, average scores increased from 2.4 to 3.5.

Of the 41 knees that underwent realignment in addition to receiving a meniscal allograft, 35 (85.4%) achieved Good to Excellent results. The authors comment on the difficulty in determining which procedure contributed the most to relieving pain.

Seven treatment failures occurred. The 3 patients who experienced locking showed unhealed grafts. As a result, they underwent meniscus removal.

Other complications included 6 patients with posterior horn tears after knee reinjury, 1 patient with an osteotomy nonunion, 2 patients with pain from their realignment hardware, and 2 patients with wound infections.

7. Fritz reported on the first 11 patients to undergo meniscal transplantation at her facility. (Fritz 1996)

   Study Population: The 11 patients had an average age of 26.4 years. An average of 41.9 months elapsed from meniscectomy to transplant.

   Results: The 6 patients with more than 1-year follow-up (average 17 months) indicated that kneeling and squatting were their most limited daily activities. Their Lysholm score averaged 71.5.

   Conclusion: Short-term functional results appear encouraging, but further research with longer follow-up times is needed before the effectiveness of meniscal transplantation can be judged.

8. Veltri reported the results of 6 lateral, 6 medial, and 2 bilateral deep-frozen and cryopreserved meniscal transplants. (Veltri 1994) The average follow-up was 8 months with 3 cases having less than 6 months follow-up.

   Study Population: The 14 subjects had an average age of 35.3 years (range 24 to 46 years), and they had undergone total meniscectomy 11.3 years earlier. Associated procedures included ACL reconstruction (10), posterior cruciate ligament reconstruction (1), and both ACL and posterior cruciate ligament reconstruction (1).

   Results: After 8 months, no patients experienced locking, recurrent effusions, or giving way. One subject developed a stitch abscess, and 2 complained of joint line pain over the allograft site.

   Of the 11 subjects with more than 6 months follow-up, 7 consented to second-look arthroscopy. Four subjects (3 medial and 1 lateral) showed complete healing to the periphery with no evidence of shrinkage. One lateral and one medial allograft failed to heal at the posterior horn. One lateral graft healed to the periphery, but the inner meniscus had frayed and degenerated. Incomplete healing did not cause any clinical symptoms, such as locking or effusion.

   Conclusion: Deep-frozen and cryopreserved meniscal allografts may heal to a well-vascularized periphery. The authors also state that while subjects achieved a high rate of periphery healing, the long-term results are unknown.

9. The researchers report the results of meniscal allograft via arthrotomy for 6 patients (4 medial and 2 lateral) after an average of 30 months. (Garrett 1991)

   Study Population: Patient age averaged 32 years, and they underwent meniscectomy 8 months to 20 years prior to transplantation. All had additional procedures at time of transplant including ACL reconstruction (3), osteochondral allograft (2), and ACL reconstruction with osteochondral allograft (1).

   Results: After an average of 30 months (range 24 to 44 months), 3 subjects had no complaints of pain and 3 claimed occasional minimal pain with occasional clicking. Patients did not experience locking. Arthroscopy in 4 cases showed healing around the entire graft circumference with firm attachment of anterior and posterior horns. None of the grafts showed evidence of shrinkage or rejection.

   Conclusion: The authors conclude that further studies and longer follow-up are necessary to assess whether meniscal transplants will prove durable, prevent degenerative changes, and enhance stability.

C. Researchers have published case studies describing successful meniscal allograft transplants.

1. Fritz examined a 28-year-old male who injured his knee at age 20. (Fritz 1996) At 22, he underwent medial meniscectomy. At 23, he underwent ACL reconstruction to address a chronic Grade III ACL tear. At 27, he underwent a transplantation with a fresh frozen, nonirradiated, medial meniscus to address pain and degenerative changes in the medial compartment. One year after transplantation, he scored a 62 out of 100 on the Lysholm scale, 75% on the Activities of Daily Living scale, and 54% on the Sports Activity scale.

2. De Boer reported on a 48-year-old man with lateral compartment osteoarthritis who had a lateral meniscectomy 20 years earlier and a partial medial meniscectomy 10 years earlier. (De Boer 1991) To treat his painful, swollen knee, physicians implanted a cryopreserved, nontissue-antigen-matched lateral meniscus.

   Three months after transplantation the man walked painlessly without crutches. Six months after implantation, diagnostic arthroscopy indicated that the transplant was normal in size and firmly fixed. After 1 year, the patient experienced no pain and returned to work.

   Additional analysis showed that the synovial membrane demonstrated a mild inflammatory response. The meniscal fibrocartilage contained metabolically active cells that showed irregular distribution and a disordered structure. The enzyme histochemical pattern indicated tissue with active cells without signs of degeneration.

   Conclusion: Analysis showed that meniscal chondrocytes survived cryopreservation and transplantation.

D. Researchers have also published case studies describing treatment failures.

1. A 32-year old male whose meniscal transplant failed underwent a DNA profile. (Debeer 2000) The subject had a meniscectomy in 1993, but later developed a Grade III chondropathy. In 1995, he underwent a cryopreserved meniscal allograft. One year later, the patient experienced a locking knee because of a loose posterior bone block. Physicians conducted a biopsy during resection.

   Analysis of DNA from the biopsy compared to DNA from blood samples indicated equivalency of tandem repeat loci between the two samples. Researchers found perivascular inflammatory infiltrate with lymphocytes, which corresponds to an immune response against donor cells. An estimated 10% to 40% of the donor cells in the transplant were viable at the time of implantation. After one year, host cells had replaced 95% of donor cells.

   The authors conclude that host cell replacement of donor cells in human meniscal allograft challenges the need for cell viability at the time of transplantation.

2. A 33-year old cyclist underwent a medial meniscectomy 19 years earlier. (Hamlet 1997) The patient reinjured his knee and did not respond to 6 months of conservative care. As a result, the patient underwent a medial meniscal allograft transplant with a cryopreserved meniscus using bone blocks.

   Three weeks later, the subject developed a knee effusion. Blood cell counts showed elevated white blood cells and an increase in lymphocytes. Ten weeks after transplantation, the subject underwent second-look arthroscopy, which showed that erythematous, hypertrophic synovium lined the joint. The detached transplant had also shrunk by over 50%.

   After resection, researcher conducted histological analysis of the tissue. The frayed inner margin appeared brittle and soft indicating degeneration. The collagen fiber matrix had lost its normal orientation. The central portion of the transplant remained acellular and avascular while the superficial layer contained lymphocyte and plasma cell infiltrate.

   The researchers postulate that a host-versus-graft rejection reaction caused the failure of the meniscal allograft.

3. Researchers examined three patients whose transplants of nontissue-antigen-matched medial menisci failed. (De Boer 1994)

   The first case study examined a 55 year-old male with increasing pain in his knee. Six months after transplantation, the patient still experienced pain. Arthroscopy showed a loosening of the midposterior part of the donor meniscus. After 12 months, researchers removed the donor meniscus. Tissue biopsies showed active cells at the anterior portion, which had remained attached to the capsule. However, degenerative cells were found at the posterior portion, which had detached from the capsule.

   The second case study described a 37-year-old female who had undergone complete medial meniscectomy 12 years earlier. She experienced pain at rest and showed arthrosis of the medial femoral condyle and tibial plateau. A cryopreserved meniscus transplant provided no pain relief after 8 months. At 20 months, she experienced locking. Arthroscopy showed a loosening of the anterior and middle part of the meniscus. As a result, physicians removed the donor meniscus and performed an osteotomy. The tissue biopsy showed an acellular and degenerate anterior horn. However, vascular ingrowth could be seen at the parts of the meniscus still attached to the capsule.

   The third case detailed a 52 year-old male who underwent meniscectomy 8 years before transplantation of a cryopreserved meniscus. At the time of transplant, he also underwent an extra-articular stabilizing procedure due to a lack of cruciate ligaments. Two years later, he experienced locking. The donor meniscus was removed because it had become detached. Most of the meniscus was avascular, acellular, and degenerative.

The researchers conclude that the long-term success of meniscal transplants depends on the ability of the meniscal fibrochondrocyte to synthesize and maintain the extracellular matrix responsible for the mechanical properties of the meniscus as well as factors that promote good vascularization.

E. CryoLife, a company specializing in cryopreservation of tissue, sent questionnaires to patients of surgeons who had performed at least 5 meniscal allograft surgeries between 1991 and 1997. (CryoLife undated) Researchers retrospectively assessed clinical outcome using a quality of life questionnaire with a modified Lysholm score. Follow-up time averaged 5.1 years (range 36 to 96 months).

Study Population: CryoLife surveyed 332 patients from 13 surgical sites throughout the US. Out of 332 patients, 136 subjects (41%) responded totaling 146 grafts. Average patient age was 35 years (range 17 to 58 years), and patients underwent transplants of the medial (97) and lateral (48) menisci.

Results: Postoperative pain level averaged 2.7, and postoperative Lysholm scores averaged 79. 80% of patients rated their knee function as normal to nearly normal as compared to their knee function before surgery. 84% of patients were able to enjoy sporting activities and 69% of patients received good to excellent postoperative scores on the Lysholm activity scale. 90% of patients reported their surgery as a success.

Complications included 2 meniscal tears, 1 case of trauma sustained 4 months after surgery, 3 stability and alignment corrections, 2 bone spurs, 1 case of swelling after consistent use, and 2 related injuries indirectly affecting knee function.

Of the 146 implants, 20 failures (14%) occurred as defined by either a partial or total graft removal. Fourteen partial removals occurred after an average of 26.8 months (range 12 to 72 months) while 6 complete graft removals occurred 34 months (range 12 to 72 months) following transplant.

V. Danish Consensus Statement

On September 5, 1998, a general consensus group of leading orthopaedic surgeons from Denmark and Sweden released its recommendation that meniscal transplantations in Denmark should not be conducted as a general treatment, but only as part of controlled trials. (Meniscus 1999)

The group also declared the following points.

They stated that the aims of a meniscus replacement following meniscus resection are:

- to reduce the pain experienced by some patients
- to prevent the degenerative changes of cartilage and the changes in subchondral bone
- to avoid or reduce the risk of arthrosis
- to restore optimally the mechanical properties of the knee joint.

Experience from the series of patients with meniscus replacement indicates that the mechanical properties of the transplants in humans are inferior to a normal meniscus, but this has not been scientifically investigated.

The indication to perform meniscus replacement is to reduce disabling pain and not to get patients back to knee-stressing activities like high-level sport.

While uncontrolled studies suggest that allografts can reduce pain, the mechanism for pain reduction remains unknown. There are no controlled studies of meniscus replacement in humans. Therefore, the evidence does not indicate "that replacement can avoid or reduce the risk for arthrosis or degenerative changes of the cartilage."

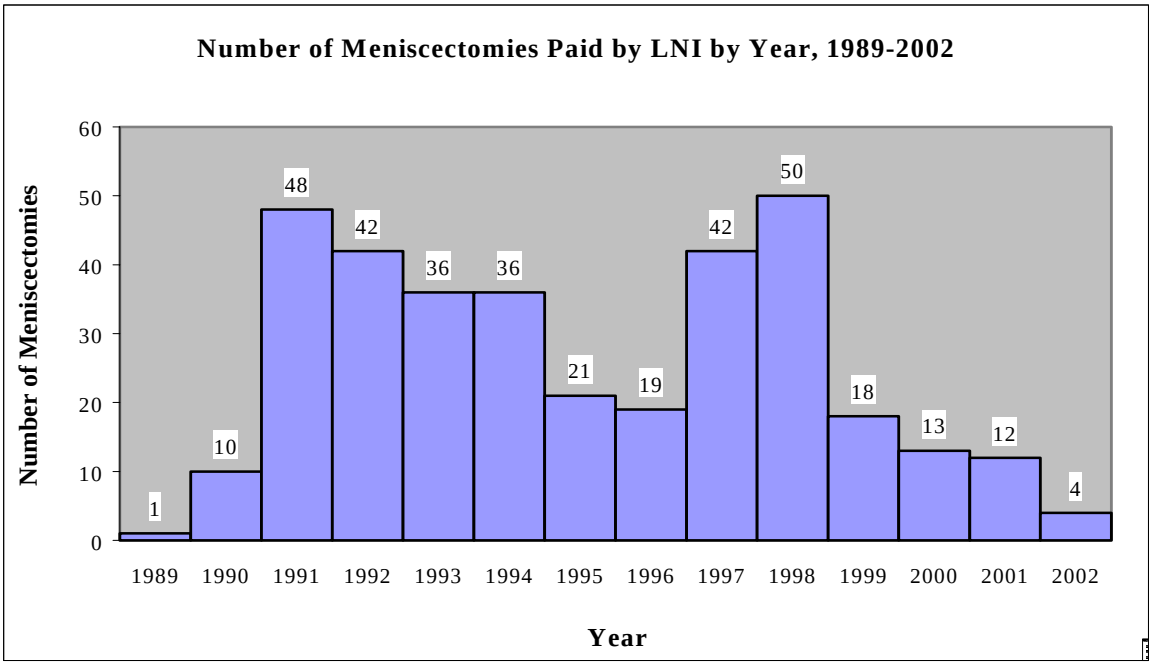
VI. Costs

A report published in 1998 estimated that graft costs ranged from $2,500 to $3,500. After adding graft cost to surgical, anesthesia, and facility charges, the author estimates that the total bill may exceed $15,000. (Shelton 1998b)

In a personal communication on October 22, 2002, a representative from Cryolife stated the price of meniscus tissue as $4,900.

VII. Department's Experience

The Department of Labor and Industries has not covered any cases of meniscal allograft transplant. However, from 1989 to 2002, the department covered 352 meniscectomies in 331 people. These cases were billed under CPT Code 27332, which reads "Arthrotomy with excision of semilunar cartilage (meniscectomy) knee; medial OR lateral." (AMA 2001) Of the 331 patients, 218 people were born after December 31, 1951 and 150 were born after December 31, 1957.



VIII. Other Insurers

Aetna covers meniscal allograft transplants for patients who meet specific criteria. Prospective patients must be less than 45 years old, have undergone a total or partial meniscectomy, and have minimal degenerative changes in a stable knee. (Aetna 2001)

Several Blue Cross Blue Shield members do not cover meniscal allograft because they deem the procedure investigational. For example, California, Iowa, Massachusetts, North Carolina, South Dakota, and the Regence Group do not cover meniscal allografts. (Blue 2002) (Blue 2001a) (Blue 2001b) (Regence 2002) (Wellmark 2001)

Humana does not cover meniscal allografts because the medical literature does not show the procedure's safety or efficacy. (Humana 2001)

IX. Conclusion

Meniscal allograft transplantation may benefit selected patients who have previously undergone total meniscectomy, but continue to experience pain.

Published short term and midterm case series data suggest that meniscal allograft provides pain relief and restores some knee function. Studies do not strongly indicate the necessity for viable donor in the graft at the time of transplantation. The data regarding meniscal allograft transplant's ability to prevent osteoarthritis remains inconclusive. Finally, researchers have not published in peer-reviewed journals any controlled studies documenting the effectiveness of meniscal allograft transplantation.